July 8, 2004

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Dear Dr. Phurrough,

On behalf of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the American College of Cardiology (ACC), and the American Hospital Association (AHA), we are writing with regard to our April 20th meeting with you and your staff on the issue of cardiac rehabilitation services. At that meeting, four key issues were raised regarding various aspects of CMS' policies for outpatient cardiac rehabilitation services. You asked our organizations to address four questions:

1. Is there statutory authority [benefit category] to pay for outpatient cardiac rehabilitation?

2. Does outpatient cardiac rehabilitation meet the "incident to" requirements as delineated in the Medicare statute and implementing regulations/instructions?

3. What role does the physician play to ensure the "incident to" requirements are being met?

4. What are the components of outpatient cardiac rehabilitation?

It is also important to note that at our meeting you made a firm commitment to us that CMS would act to preclude its contractors from issuing revisions to local policies affecting cardiac rehabilitation until the final OIG report was submitted to CMS and you had the opportunity to review the report and formally begin the process for any changes in the existing national coverage policy. One Medicare contractor, UGS, has taken the opposite approach and issued a revised policy that precludes emergency physicians from providing emergency coverage to cardiac rehabilitation programs. Such action is contrary to the specific statement you made to all of us and, in our view, is contrary to existing national policy as spelled out in 35-25 of the Coverage Issues Manual. **We urge you to again ask UGS as well as your other contractors to refrain from issuing policy revisions pending further action from CMS nationally.**

The AACVPR, ACC and AHA believe that outpatient cardiac rehabilitation services are an appropriate part of the "incident to physician services" benefit category as established in the Medicare statute. Cardiac rehabilitation is defined as up to 36 sessions of electrocardiogram monitored exercise training and heart disease risk factor modification

after coronary artery bypass surgery, following onset of stable angina pectoris, or within one year of acute myocardial infarction.

We believe that cardiac rehabilitation services are authorized under Section 1861(s)(2)(B), which authorizes payment for services that are "***incident to physicians' services rendered to outpatients…***" This position is reinforced by a review of the Medicare Intermediary Manual (3112.4), the Medicare Hospital Manual (Section 230.4 A) and the recently codified Medicare Benefit Policy Manual (20.4.1), all of which elaborate on this benefit category by providing guidance as to what constitutes "incident to" services.

Our responses to the questions, detailed below, represent a consensus from our three organizations.

Question 1: Is t[illegible] statutory authority [benefit category] to pay for outpatient cardiac rehabilitation?

There are two key provisions that must be met in order for a service to be considered a covered benefit. First, there must be a reference to the benefit in the statute, either directly or indirectly. Secondly, the statute requires that a service must be reasonable and necessary. While there is no specific reference to outpatient cardiac rehabilitation in Title XVIII, it is a covered service under the "incident to" provisions of Section 1861(s)(2)(B) of the statute which provides broad discretionary authority to the Secretary to address reasonable and necessary services that are not specifically mentioned as covered services. Many other services, not otherwise having a statutory benefit category, are covered by Medicare through the "incident to" provisions, as identified in Section 35 of the Coverage Issues Manual. Examples would include treatment for drug abuse, treatment of alcoholism, chemical aversion therapy, biofeedback therapy and diathermy treatment.

Question 2: Does cardiac rehabilitation meet the "incident to" requirements as delineated in the Medicare statute and implementing regulations/ instructions?

It is vitally important to recognize that Section 1861(s)(2) of the Social Security Act has two specific and distinctly different references to the general "incident to" services benefit category. The first reference, found in 1861(s)(2)(A), refers to a physician's office setting and the services provided by, for example, nurses, that are incident to the physician's services. The second reference, which follows immediately in the statute, refers to "hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services…." Medicare has long recognized the need to provide clarity and specification regarding "incident to" services and has attempted to do so in its various manuals.

There are several other examples of outpatient therapeutic services that are covered under the "incident to" provisions of 1861(s)(2)(B), most notably wound therapy and infusion

therapy. These services are virtually identical to the key components of cardiac rehabilitation in that all are ordered by a physician, the services are provided by hospital personnel, and are considered the standard of care for the treatment of diagnoses identified in the Medicare Hospital Coverage Manual. As noted above, a review of the covered medical procedures identified at Section 35 of the Coverage Issues Manual clearly signals that the presence of specific statutory reference is not necessary for coverage.

We must assume that although not specifically identified in the statute, outpatient cardiac rehabilitation services (which are identified in the Coverage Issues Manual as legitimate covered services) are services for which coverage should be provided through the "incident to" provisions and the "reasonable and necessary" provisions of the statute.

A detailed review of these manual instructions to determine the applicability of cardiac rehabilitation as a Medicare covered service must reasonably conclude that cardiac rehabilitation is a covered service in that it meets all criteria identified in the various manual instructions and statements.

The Medicare Hospital Manual includes the following provision:

> *230.4 Outpatient Therapeutic Services-*
>
> *A. Coverage of Outpatient Therapeutic Services-*
>
> *Therapeutic services which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services.*
>
> *To be covered as incident to physicians' services, the services and supplies must be furnished on a physician's order by hospital personnel under hospital medical staff supervision in the hospital, or if outside the hospital….*

Clearly, cardiac rehabilitation meets all of these criteria:

- The services are incident to the treatment of the specific qualifying clinical criteria identified in 35.25 of the Coverage Issues Manual.

- The services are furnished only on a physician's order by hospital personnel under hospital medical staff supervision in the hospital. While there is admittedly confusion among Medicare contractors (as highlighted by the series of reviews posted on the Office of the Inspector General [OIG] Web site) regarding which specific physician triggers the "incident to" cardiac rehabilitation services, in reality CMS must recognize that there are three common scenarios, all similar in the practical diagnosis and treatment of cardiac related disease.

- A patient's primary care physician prescribes cardiac rehabilitation. In addition to the cardiac rehabilitation medical director, this physician also serves to meet the "incident to" requirement that a physician see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.

- A patient's specialist (usually a cardiologist) prescribes cardiac rehabilitation. As in the above case, this physician also serves to meet the "incident to" requirement that a physician see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.

- A patient is referred by a hospital's house physician to cardiac rehabilitation after discharge. This hospital house physician can also serve to meet the "incident to" requirement that a physician see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.

Perhaps most importantly, the provision of cardiac rehabilitation services also meets the "reasonable and necessary" statutory requirement of Title XVIII as it is ordered by a physician and contributes to the treatment of a specific diagnosis(es).

The Medicare Intermediary Manual includes the following provision:

3112.4 Outpatient Therapeutic Services-

A. Coverage of Outpatient Therapeutic Services-Therapeutic services which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services.

To be covered as incident to physicians' services, the services and supplies must be furnished as an integral, although incidental, part of the physician's professional service in the course of diagnosis or treatment of an illness or injury. The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. This does not mean that each occasion of service by a non-physician need also be the occasion of the actual rendition of a personal professional service by the physician. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment. The physician supervision

requirement is generally assumed to be met where the services are performed on hospital premises; the hospital medical staff that supervises the services need not be in the same department as the ordering physician.

[Note: The newly created **Medicare Benefit Policy Manual** includes identical language appears in 20.4.1.]

Again, clearly, cardiac rehabilitation meets all the existing manual criteria addressing "incident to" services. In summary, cardiac rehabilitation services are "*incident to*" services as they are furnished as an integral, although incidental part of the physician's professional service in the course of treatment for the diagnoses identified in 35.25 of the Medicare Coverage Issues Manual.

Cardiac rehabilitation is furnished only on a physician's order by hospital personnel under a physician's supervision. (See section below, addressing the role of physician supervision in cardiac rehabilitation.)

Question 3: What role does the physician play to ensure the "incident to" requirements are being met?

Physician Supervision: Just as cardiac rehabilitation, wound therapy, and infusion therapy are not directly referenced in the Medicare statute, the concept of "physician supervision" of diagnostic and therapeutic services is likewise not mentioned in the Medicare statute. Rather, it would appear that physician supervision is an administrative concept developed by CMS to address certain aspects of "incident to" services.

There are, in fact, three levels of physician supervision embedded in Medicare rules and regulations, including personal supervision, direct supervision, and general supervision.

- **Personal physician supervision** is generally applied to clinical situations where actual physician presence during the procedure/service is deemed to be medically appropriate.

- In the context of cardiac rehabilitation "***direct supervision*** *means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted. It does not require that a physician be physically present in the exercise room itself, provided the contractor does not determine that the physician is too remote from the patients' exercise area to be considered immediately available and accessible*."

- **General supervision** usually applies to simple supervisory and administrative responsibilities assigned to physicians rather than specific clinical responsibilities that contribute to the diagnosis and/or treatment of specific patients.

We believe that CMS should consider restructuring its requirements for physician involvement and supervision of cardiac rehabilitation in order to reflect not only the

findings of the recent series of reviews conducted by the OIG, but also the prevailing standard of care for hospital based cardiac rehabilitation. This would require modest, but appropriate changes:

a. **There is no clinical basis for a requirement that a physician be in the proximate area of the exercise room.** Medicare has no such requirement for physician supervision of intensive care/critical care units in hospitals where clearly, more unstable inpatients are provided care. Hence, there is no clinical logic to maintain a requirement for such physician presence in the area where stable monitored outpatients are participating in cardiac rehabilitation.

b. **Medicare should require hospitals to identify a specific physician to serve as the "medical director" of cardiac rehabilitation.** Among this physician's duties, would be responsibility for ensuring the provision of appropriate documentation in order to meet Medicare coverage and payment requirements for outpatient cardiac rehabilitation services. Additionally, the medical director would assume responsibility for ensuring that Medicare's "*incident to*" requirements (*a physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen)* are being met.

c. **Medicare should explicitly re-state, in concurrence with its own policies and the findings of the OIG, that "The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises."** As the OIG found, most hospitals have interpreted this statement of Medicare policy to mean that a physician is available to quickly respond to a life-threatening emergency that may occur in the course of a patient's cardiac rehabilitation treatment. It is the responsibility of the "medical director" to ensure that on any given day, specific physician(s) know they are responsible for such emergency coverage or that an established "code team" policy in the hospital will guarantee the expeditious arrival of one or more physicians to address any life-threatening emergency that arises in the cardiac rehabilitation exercise area. In the case where emergency physicians are providing such coverage, hospitals currently have policies and procedures in place to ensure physician coverage in the event that emergency physicians are not available to respond to codes. CMS also should explicitly state that a hospital's established "code team" protocol will satisfy this presumption of physician supervision for cases of emergency in a hospital setting.

Physician Involvement: Clearly, the OIG recognized the need for CMS to clarify the "incident to" requirements. We concur with the OIG that physician involvement in cardiac rehabilitation is critical to the patient's success in achieving the specific goals identified at the outset of the program. We recognize that physician involvement is critical to the current policy whereby a "*physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen*."

To reiterate points made above, physician involvement is not a matter of one specific pre-determined physician personally seeing the patient periodically and sufficiently often. To the contrary, just as the OIG reports indicated, there are a limited number of scenarios that can meet the current requirement.

a. A beneficiary may choose to see his/her own **primary care physician** during the course of the cardiac rehabilitation program to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.

b. A beneficiary may choose to see his/her specialist/**referring physician** during the course of the cardiac rehabilitation program to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.

c. A beneficiary may choose to see the **rehabilitation program's medical director or program affiliated physician** during the course of the cardiac rehabilitation program to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.

In all of these scenarios the beneficiary retains the freedom to choose his/her caregivers and the patient is seen by a physician periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.

Question 4: What are the components of cardiac rehabilitation?

Exercise therapy is the cornerstone of cardiac rehabilitation. However, contemporary cardiac rehabilitation also includes multi-faceted treatment of a chronic, progressive, and potentially reversible disease.

Comprehensiveness

Cardiac rehabilitation programs have long been recognized as integral to the comprehensive management of patients with cardiovascular disease.[1] The accepted definition of cardiac rehabilitation states that "*cardiac rehabilitation services are comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling."* This multi-faceted process "*is designed to limit the adverse physiologic and psychological effects of cardiac illness, reduce the risk of sudden death or re-infarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the patient's psychosocial and vocational status."* [2] Provision of these services is physician-driven and implemented by a team of health care professionals, including nurses, exercise physiologists, dietitians, health educators, behavioral medicine specialists, and other health care professionals.

In 2000, the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation published a joint scientific statement

encouraging cardiac rehabilitation programs to *contain specific core components that aim to optimize cardiovascular risk reduction, foster healthy behaviors, and compliance to those behaviors, reduce disability and promote an active lifestyle for patients with cardiovascular disease.* [3]

Scientific Evidence

Morbidity/Mortality Data

There is evidence-based consensus among major scientific organizations that regular exercise and risk factor modification favorably alter the clinical course of coronary heart disease. [1, 2] Multiple systematic reviews have demonstrated significant reduction in total and cardiovascular mortality of 27-31% in patients who participate in cardiac rehabilitation programs. [2,4] Medically supervised exercise has been proven to halt progression, enhance regression of angiographic stenoses, and significantly reduce hospital readmission rates when compared to patients receiving only percutaneous transluminal coronary angioplasty or coronary stenting.[5,6] Improved endothelium-dependent vasodilation resulting from exercise training may represent the most important mechanism to explain the marked reduction of myocardial ischemia. [7,8]

Maximal exercise capacity has been shown to be a more powerful predictor of mortality among men than other established risk factors for cardiovascular disease. [9] A number of studies have demonstrated a significant gain in maximal exercise capacity in a cardiac exercise training group compared to control or usual care group [6,10]

Cost Effectiveness Data

Several studies have documented that cardiac rehabilitation services are cost effective by reducing recurrent hospitalization and health care expenditures. [11,12,13] These findings compare favorably with the cost effectiveness of other preventive measures in cardiology.[14] It was the conclusion of the Agency for Health Care Policy and Research (AHCPR) Guidelines that cardiac rehabilitation is a cost-effective use of medical care resources (pg 21). A more recent, randomized, 12-month study compared patients receiving exercise training to patients who received percutaneous coronary angioplasty (PCI). [10] The interventional strategy was twice the cost as a result of higher initial expenses of the PCI procedure and more frequent re-hospitalizations and coronary interventions in this group.

Underutilization

A recent report released by the Centers for Disease Control (CDC) in November, 2003 pointed to the underutilization of cardiac rehabilitation services, despite evidence that cardiac rehabilitation has been associated with substantially improved survival rates, greater exercise tolerance, fewer cardiac symptoms, lower blood fat levels, cessation of smoking, improved psychosocial well-being, and reduced risk for illness. Their conclusion was that including cardiac rehabilitation in all intervention plans for eligible patients with coronary heart disease remains a key strategy for reducing further disability.[15]

Summary

Cardiac rehabilitation improves functional capacity, increases survival, and limits, possibly decreasing progression of coronary artery disease. We must continue to work together to clarify the nuances of the "incident to physician services" benefit category as it applies to cardiac rehabilitation.

Thank you for your consideration of these comments. We look forward to working with you and others at CMS as this issue continues to develop.

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